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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/259,929	03/01/1999	ANTHONY CERAMI	10162-004-99	5875

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EXAMINER	
CHONG, YONG SOO	
ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
06/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/259,929	CERAMI ET AL.	
	Examiner	Art Unit	
	Yong S. Chong	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8-14,17-19,48,50,58 and 59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8-14,17-19,48,50,58 and 59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Claim(s) 7, 15-16, 20-47, 49, 51-57 have been cancelled. Claim(s) 1-6, 8-14, 17-19, 48, 50, 58-59 are pending. Claim(s) 1 has been amended. Claim(s) 1-6, 8-14, 17-19, 48, 50, 58-59 are examined herein.

Applicant's arguments have been fully considered but found not persuasive. All rejections are maintained for reasons of record and are repeated below for Applicant's convenience.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-6, 8-14, 17-19, 48, 50, 58-59 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 57-76 of copending Application No. 10/783,052. Although the conflicting claims are not identical, they are not patentably distinct from each other because the

claims sufficiently overlap in scope. The latter claims are directed to a method of modulating the immune response in a mammal to an antigen by implanting a device comprising a polymeric material containing the antigen within a second polymeric material, where all of the polymers overlap in scope and the forms of administration are disclosed.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's request that the double patenting rejection(s) be held in abeyance until allowable subject matter is identified is acknowledged.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham vs John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-6, 8-14, 17-19, 48, 50, 58-59 are rejected under 35 U.S.C. 103(a) as being obvious over Barr et al. (US Patent 5,593,697) in view of Andrianov et al. (US Patent 5,529,777).

The instant claims are directed to a method of modulating the immune response in a mammal to an antigen by implanting a device comprising a polymeric material containing the antigen within a second polymeric material.

Barr et al. teach a pharmaceutical implant comprising a water insoluble material containing an antigen within a polymer coat (abstract) for the prophylactic or therapeutic vaccination (col. 3, lines 16-21) of a mammal (col. 4, lines 32-36). Vaccines against bacterial, viral, fungal, or protozoal infections of animals or humans may be utilized in the device of this invention (col. 6, lines 61-64). Barr et al. disclose that those skilled in the art will be able to recognize the various biocompatible polymers that can be used in this invention (col. 3, lines 52-55). One or more layers of different polymers may be used and when exposed to normal physiological pH conditions, the rupture time of the antigen from the polymer coat is typically between 14 to 45 days (col. 4, lines 9-14). This bilayer film coating forms an impermeable barrier to the antigen until such time for rupture (col. 5, lines 1-16). The preferred polymers are but not limited to polyethylene, silicone, acrylic resins, and polylactide-glycolide copolymers (col. 5, line 60 to col. 6, line 15). Barre et al. discloses that those skilled in the art will also appreciate that other biodegradable polymers may be used in this device (col. 6, lines 45-49). The thickness

and permeability of the films can be varied by the type of polymer and/or the addition of more than one polymer so as to form a delayed release formulation (col. 5, lines 46-57).

It is noted that the device as disclosed by Barr et al. will intuitively attract cells of the immune system to encounter the antigen and modulate an immune response, because of the fact that a composition and its properties are inseparable. Applicant has argued that the device that Barr et al. discloses includes an interior and exterior film, which allows fluid to access the core that promotes swelling and subsequent release of the antigen. Thus, a perforated impermeable diffusion barrier would be contrary to the goals of Barr et al. This is found not persuasive since Barr et al disclose the same material used for the diffusion barrier. Despite the absence of a "diffusion barrier" per say in the disclosure of Barr et al., one is actually present in the device. Furthermore, the release of the antigen is irrelevant because Barr et al. discloses the rupture period to be well after 10 days.

Finally, Barr et al. disclose that the invention is susceptible to variations and modifications other than those specifically described (col. 15, lines 20-23). Thus, it is intuitive to optimize the invention so that the antigen can be repeatedly introduced to the device before or after implantation. Furthermore, it is obvious to one of ordinary skill to optimize the device so that the antigen is immediately bioavailable or in a delay release formulation.

"When the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimal or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955); see also *In re Peterson*,

315 F. 3d at 1330, 65 USPQ 2d at 1382 "The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages." MPEP 2114.04.

However, Barr et al. fail to disclose specifically the use of antigens for the preparation of a hybridoma.

Andrianov et al. teach antigens encapsulated by polymers to form microparticles to induce an immune response in an animal (col. 25, lines 50-57). The preferred biodegradable polymers include polycarbonates, polyesters, polyurethanes, polyamides, polyvinyl alcohol (PVA), gelatin, alginate, polyvinylpyrrolidone (PVP), methyl cellulose (col. 4, lines 1-37), polystyrene, and copolymers of the polymers or monomers thereof (col. 5, lines 9-21). Andrianov et al. also disclose encapsulating hybridoma cells in the microspheres (example 1).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to have used hybridoma cells as the antigen as taught by Andrianov et al. in the device as taught by Barr et al.

A person of ordinary skill in the art would have been motivated to use hybridoma cells because of the teaching by Andrianov that hybridoma cells can be encapsulated in microspheres for the purpose of modulating the immune system. One of ordinary skill in the art would have had a reasonable expectation of successfully forming a device comprising hybridoma cells as the antigen for the modulation of the immune system in mammals.

Response to Arguments

Applicant argues that the Barr device has a compressed solid core, whereas the instant invention has a porous matrix, therefore the immune cells would not be able to enter the compressed solid core of the Barr device.

This is not persuasive because Applicant has misinterpreted the Barr reference. The core referred to in the Barr reference is disclosed to be comprised of the antigen or biologically active material and not the coating. The bilayer coating is composed of a porous matrix made of the same polymers in the instant invention. Moreover, these polymers are described as biodegradable single films that become porous by forming holes, designed to allow contact between the antigen and the outside environment.

It is noted that the device as disclosed by Barr will intuitively attract cells of the immune system to encounter the antigen and modulate an immune response, because of the fact that a composition and its properties are inseparable. Applicant's arguments are found not persuasive since Barr disclose the same material used for the diffusion barrier. Despite the absence of a "diffusion barrier" per say in the disclosure of Barr et al., one is actually present in the device. Furthermore, the release of the antigen is irrelevant because Barr discloses the rupture period to be well after 10 days. Applicant's disclosure corroborates this by stating that the device is composed of biodegradable materials, which eventually degrade within the body. It is further noted that the biodegradable materials in the current invention are the same polymers disclosed by the prior art references above.

"Products of identical chemical composition can not have mutual exclusive properties." Any properties exhibited by or benefits from are not given any patentable weight over the prior art provided the composition is inherent. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the disclosed properties are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01. The burden is shifted to the applicant to show that the prior art product does not inherently possess the same properties as the instantly claimed product.

Applicant argues that because the Barr device and the current device have been designed to achieve different ends, it is not obvious to interchange similar biocompatible and biodegradable polymers even though the polymers have the same attributes.

In response, Barr discloses that it is well known in the art to combine an immediate release implant with a delayed release, where the delayed pulse is typically 10-60 days after implantation (col. 3, lines 4-9). Although no "immediate release" is disclosed per say in the Barr device during the first 10 days before release of the antigen from the device, Examiner notes that immune cells do indeed come into contact with the antigen within the device because the same or functionally equivalent biodegradable polymers are disclosed. Nonetheless, Applicant's disclosure corroborates this by stating that the device is composed of biodegradable materials, which eventually degrade within the body. In essence, the ultimate use is the same in both cases because the antigen and immune cells are eventually discharged from the device after total degradation of the biodegradable polymers.

Applicant argues that the devices are not made of the same chemical compositions; specifically that Barr discloses the use of at least one water-soluble excipient. This is not persuasive because the instant claims use "comprising" open language, which does not preclude the inclusion of excipients in the compositions.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

YSC

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER